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In Re: Patent Term Extension  
Application for  
U.S. Patent No. 5,510,106

## NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,510,106, which claims the veterinary biologic product FEL-O-FAX LvK/FIV vaccine, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,348 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 1,348 days.

The period of extension has been calculated using the United States Department of Agriculture's determination of the length of the regulatory review period published in the Federal Register of September 17, 2007 (72 Fed. Reg. 52847). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} \text{ (Testing Phase) + Approval Phase} \\ &= \frac{1}{2} (0) + 1,348 \text{ days} \\ &= 1,348 \text{ days (3.7 years)}\end{aligned}$$

Since the regulatory review period began October 15, 1999, after the patent issued (April 23, 1996), the entire regulatory review period has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.: 5,510,106

Granted: April 23, 1996

Original Expiration Date<sup>1</sup>: January 4, 2011

Applicant: Janet K. Yamamoto et al.

Owner of Record: The Regents of the University of California

Title: Methods and Compositions for Vaccinating Against Feline Immunodeficiency Virus

Product Trade Name: FEL-O-FAX LvK/FIV vaccine

Term Extended: 1,348 days

Expiration Date of Extension: September 13, 2014

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE      By FAX: (571) 273-7755  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450.

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.



Mary C. Till  
Legal Advisor  
Office of Patent Legal Administration  
Office of the Deputy Commissioner  
for Patent Examination Policy

cc: U.S. Department of Agriculture  
Animal and Plant Health Inspection Service  
Center for Veterinary Biologics  
510 South 17th Street, Suite 104  
Ames, IA 50010

RE: FEL-O-FAX LvK/FIV vaccine  
Docket No.: APHIS-2007-0121

Attention: Dr. Richard Hill

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<sup>1</sup>Subject to the provisions of 35 U.S.C. § 41(b).